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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,685	01/18/2005	Junichi Oka	10921.0270USWO	2163
52835 7590 08/07/2008 HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902			EXAMINER	
			WRIGHT, PATRICIA KATHRYN	
MINNEAPOLIS, MN 55402-0902			ART UNIT	PAPER NUMBER
			1797	•
			MAIL DATE	DELIVERY MODE
			08/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/521.685 OKA, JUNICHI Office Action Summary Art Unit Examiner KATHRYN WRIGHT 1797 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 08 May 2008. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1.3-6 and 8-17 is/are pending in the application. 4a) Of the above claim(s) 18-20 is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1, 3-6 and 8-17 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/S5/08)
 Paper No(s)/Mail Date \_\_\_\_\_\_.

Attachment(s)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

Notice of Informal Patent Application

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### DETAILED ACTION

#### Status of the Claims

This action is in response to papers filed May 08, 2008 in which claims 1, 5, 8-10,
 and 15-16 were amended, claims 2 and 7 were canceled and claims 18-20 were added. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated November 08, 2007 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection.

Claims 1, 3-6, 8-20 are under prosecution.

#### Election/Restrictions

2. Newly submitted claims 18-20 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: new claims 49-58 are distinct from claims 1, 3-6 and 8-17 because these new claims are directed to a substantially different apparatus that was not previous searched or considered. New claims 18-20 recite "wherein each of the positioning portions includes a first recess portion sized sufficiently to receive the target analyte and a second recess portion arranged between the first recess portion and a respective one of the through-holes in communication therewith, the second recess portion being sized smaller than the target analyte for prevent entry of the target analyte into the second recess portion "a plurality of assay chambers and a tip portion", whereas claims 1, 3-6 and 8-17 do not require a

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first and second recess portion. Thus, a search for one apparatus would not necessary yield results relevant to the other apparatus and there would be a serious burden on the Examiner if restriction were not required.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 18-20 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

## Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
  - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 4. Claims 1, 3-6, 8-9, and 12-17 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The optical detector is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The claims are drawn to an analyzing device, however no element is claimed to enable the system to function as such. The optical detector (83) disclosed throughout the specification is not claimed as an element of the device (see pages 4 and 10-14 of the specification), as such it is unclear how the rotating body can function as an "analyzing device". Also, note that the specification as originally filed does not provide enablement for any other type of detector except for an optical detector.

EST.

#### Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the
examiner should be directed to P. Kathryn Wright whose telephone number is 571-2722374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM,

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. Kathryn Wright/
Patent Examiner, Art Unit 1797
pkw